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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,187	03/24/2004	Joseph S.M. Peiris	V9661.0078	4585

7590 07/25/2005

Dickstein Shapiro Morin & Oshinsky LLP
1177 Avenue of the Americas
New York, NY 10036-2714

EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,187	PEIRIS ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *4-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/13/04, 3/24/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.D

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on May 4, 2005 is acknowledged. Applicant traverses the requirement for election of species within the group. On reconsideration, in this application, examination of the species recited in claims 1-3 is not seen as unduly burdensome, so the requirement for election of species in group I is withdrawn. Because applicant did not distinctly and specifically point out the supposed errors in the restriction between groups, restriction requirement, the election of group I has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 4, 2005.

Claim Rejections - 35 USC § 112

Claims 1-3, 11, 12, 14-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3 are drawn to a nucleic acid molecule "consisting essentially of" a recited sequence. The MPEP cites In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) for the meaning of this phrase: "The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention." However, the specification does not make clear what applicants regard as constituting a material change in the basic and novel

characteristics of the invention. Therefore, the scope of claims 1-3 is indefinite. In addition, claims 11, 12, and 14-21 recite products "having" a recited sequence. In the context of these claims, it is not clear if "having" is meant to be equivalent to "comprising", or equivalent to "consisting of." Therefore the scope of these claims is also indefinite.

Priority

For the purposes of applying prior art, the effective dates of the various claims are as follows:

Claims 1, 11, 14-16, 20, effective date May 5, 2003, because there are no blazemarks pointing to the specific oligonucleotides SEQs 2471-2473 prior to their disclosure as SEQs 24-26 in Figure 17 of application 60468139.

Claims 2, 3, 12, 17-19, 21, effective date May 16, 2003, because there are no blazemarks pointing to the specific oligonucleotides SEQs 2474-2476 prior to their disclosure as SEQs 27-29 in Figure 17 of application 60471200.

Claim 13, effective date 3/24/2004. This claim involves a genus, "primers derived from a nucleotide sequence of the hSARS." The specification discloses one species of the genomic sequence of hSARS. From this disclosure one cannot predict the sequences of the entire genus of hSARS isolates. Prior to May 16, 2003, there was only a very small number of hSARS variant sequences publicly known, so even the combination of the teachings of the specification with the knowledge in the prior art was limited to a very small number of species. Therefore, it is concluded that the disclosure, as of May 16, 2003, was not sufficient to reasonably convey possession of the full

genus of "nucleotide sequence of the hSARS." Therefore benefit of priority is denied for generic claim 13. Note, claim 13 is not rejected on the grounds of inadequate written description, because of advances in the state of the art of SARS genomic sequences between the latest priority date of May 16, 2003 and the actual filing date of March 23, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

In making the following rejections, "consisting essentially of" and "having the sequence" are construed to mean "comprising."

Claim 13 is rejected under 35 U.S.C. 102(a) as being clearly anticipated by Peiris et al (Lancet 361:1319-1325, published online April 8, 2003) or Drosten et al (New England Journal of Medicine 348:1967-1976, published online April 10, 2003) or Ksiazek et al (New England Journal of Medicine 348:1953-1966, published online April 10, 2003).

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank locus AY274119. The Genbank entry discloses an isolated nucleic acid which comprises SEQ ID NOs: 2471-2476, thereby meeting each and every limitation of these claims. See positions 17703-27, 17770-46, 17745-30, 28187-207, 28271-47, 28230-45. This Genbank entry was publicly available on April 14, 2003. Please note, the website

comprises SEQ ID NOs: 2471-2476, thereby meeting each and every limitation of these claims. See positions 17703-27, 17770-46, 17745-30, 28187-207, 28271-47, 28230-45. This Genbank entry was publicly available on April 14, 2003. Please note, the website "SARS-associated Coronavirus" is cited as evidence that similar sequence data was publicly available 2 days earlier.

Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by McSwiggen et al WO 2004/092383. McSwiggen claims priority to 60/462,874, which describes and enables the claimed invention prior to applicant's effective date. McSwiggen teaches a nucleic acid which contains only 3 residues added to applicant's SEQ ID NO: 2476, see Table II, page 183, the line beginning with "28277".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank locus AY274119. These claims differ from the reference in requiring the nucleic acid to be in a container. While the reference does not specifically teach a container, it is conventional to keep nucleic acids in a container such as a capped tube. Therefore it would have been very obvious to place the nucleic acid disclosed by the reference (or any fragment thereof) inside a container.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al WO 2004/092383. This claim differs from the reference in requiring the nucleic acid to be in a container. While the reference does not specifically teach a container, it is conventional to keep nucleic acids in a container such as a capped tube. Therefore it would have been very obvious to place the nucleic acid disclosed by the reference inside a container.

Claims 11, 12, 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peiris et al (Lancet, published online April 8, 2003) or Drosten et al (New England Journal of Medicine 348:1967-1976, published online April 10, 2003) or Ksiazek et al (New England Journal of Medicine 348:1953-1966, published online April 10, 2003), any of the preceding in view of Genbank locus AY274119. Each of the primary references teaches a PCR method for detecting the SARS virus. They differ from the claimed invention in requiring probes and primers from a different segment of the genome. However, the Genbank locus teaches an entire viral genome. It would have been within

the ordinary skill of the art to choose any segment of the genome for probes and primers, as an alternative to the particular segments chosen in the reference, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 11, 13- 16, 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 20, 23, 26, 28, 29, 31, 32, 75, 77, 79, 136-139, 158 of copending Application No. 10/808121. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant seqs 2471-2473 are fragments of seqs 1 and 11 in the copending application, and therefore both sets of claims encompass the same nucleic acids and methods of analyzing nucleic acids amplified from SARS virus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that there are a large number of copending applications involving many claims to nucleic acids and fragments thereof, and a large number of SEQ IDs. The SEQ ID numbers are not consistent across all of the applications, making it difficult to determine whether or not two sets of claims involve related sequences. Applicant is requested to inform the examiner which claims in copending applications are drawn to products or methods that encompass the instant claimed products and methods, or otherwise conflict with the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/21/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER